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09/830,511	04/26/2001	Hans-Peter Saluz	F-6954	8214

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Jordan & Hamburg
122 East 42nd Street
New York, NY 10168

EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,511

Applicant(s)

SALUZ ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7 and 9-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Drawings

1. The drawings were received on 28 Aug. 2003. These drawings are acceptable in view of the comments in the office action dated 26 March 2003.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the rigid frame with an array of holes as recited in claim 12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-5, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tretyakov et al. (Russian Journal of Bioorganic Chemistry) in view of Dannoux et al. (WO 98/19794).

With respect to claim 1, the reference of Tretyakov et al. discloses an ultrathin-walled multiwell plate device (2) that includes an array of small-volume wells of identical height with the similarly shaped sample wells formed in the top surface of a heat block (1). With respect to the claim limitation that the average thickness of the walls is 20-40 microns, this reference is considered to meet this claim limitation since the device of Tretyakov et al. and the device of the instant invention are formed from a material of the same starting thickness, 60 microns, and the wells are formed using the same method, thermal vacuum-formation method, and result in a final volume of 30 microliters which is within the claimed range of 16-85 microliters.

Claim 1 differs by reciting that the plate device includes "a rigid frame fixed to the plate configured to provide support for said plate when outside of the heat block".

While the reference of Tretyakov et al. discloses a frame member (4), the reference is silent as to whether or not it provides support for the plate when not positioned in the heat block.

The reference of Dannoux et al. discloses that it is known in the art to support a plastic sheet of wells using a rigid frame (8) so as to facilitate manual or automatic handling operations of the plate (See page 8, lines 3-13).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was to provide the plate device of the primary reference with a rigid frame so as to facilitate manual or automatic handling of the plate device, as is suggested by the prior art of Dannoux et al.

With respect to the shape of the wells of claim 3, Figure 1 of Tretyakov et al. depicts the wells as having a conical shape.

With respect to the decreasing thickness of claim 4, the instant specification recites that the decreasing thickness results from the thermal vacuum-formation method employed which is the same method of formation disclosed by the reference of Tretyakov et al.

With respect to the thermoformation in a negative mold of Claim 5, Figure 1 of Tretyakov et al. depicts the use of a negative mold.

With respect to the deformable wall of claim 7, in view of the disclosed thickness of the material used to manufacture the wells, the walls would inherently be deformable.

With respect to the claimed well volume of claim 8, the reference of Tretyakov et al. discloses using a well volume of 30 microliters.

With respect to claims 10 and 11, while the reference of Dannoux et al. discloses a rigid frame member, the reference is silent as to the material of the frame member and/or thickness of the member. However, based merely on the size of the well plate and/or the desired amount of support, it would have been obvious to one of ordinary skill in the art to determine the optimum material of construction and/or thickness of the frame member while providing the required support for manual and/or automated handling of the well plate.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tretyakov et al. (Russian Journal of Bioorganic Chemistry) in view of Dannoux et al. (WO 98/19794) and Sanadi (US 5,741,463).

The combination of the references of Tretyakov et al. and Dannoux et al. has been discussed above.

Claim 12 differs by reciting that the rigid frame is injection molded and includes an array of holes matching the array of wells.

The reference of Sanadi discloses that it is known in the art to provide a tray carrier (16) for supporting a well plate device (3). The tray carrier (16) includes an array of holes (17) matching the array of wells (4) in the well plate device (3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a tray carrier as suggested by the reference of Sanadi with the well plate of the modified primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting a well plate for manual and/or automated handling.

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8. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tretyakov et al. (Russian Journal of Bioorganic Chemistry) in view of Dannoux et al. (WO 98/19794) and Atwood et al. (US 5,710,381).

The combination of the references of Tretyakov et al. and Dannoux et al. has been discussed above.

With respect to claim 13, while the reference of Tretyakov et al. discloses a heat block having sidewalls equal in height to the heat block wells (See Figure 1), the claim differs by reciting that the heat block is apertureless.

The reference of Tretyakov et al. discloses that the heat block doubles as the thermoforming mold and the apertures are present so as to apply a vacuum to the film so as to form the wells in the heat block.

The reference of Atwood et al. discloses that apertureless heat blocks for thermocycling are known in the art (See Figures 1A and 1B).

In view of these disclosures, it would have been obvious to one of ordinary skill in the art to employ the well plate of the reference of the modified primary reference in an apertureless heat block for the known and expected result of employing the well plate in an alternative means recognized in the art for performing thermocycling. Use of a separate heat block would allow the thermoforming heat block to be used to form additional plates while a PCR reaction is being performed in an apertureless heater block. Apertures would not be required since the block would not be used for thermoforming a well plate.

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Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3-5, 7, 9-11 and 13-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,556,940 in view of Dannoux et al. (WO 98/19794).

Claims 1-21 of U.S. Patent No. '940 encompass a thermocycler device and well plate device that is substantially the same as that instantly claimed.

The instant claims differ by reciting that the well plate device includes a rigid frame for supporting the plate outside the heat block.

The reference of Dannoux et al. discloses that it is known in the art to support a plastic sheet of wells using a rigid frame (8) so as to facilitate manual or automatic handling operations of the plate (See page 8, lines 3-13).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was to provide the plate device of the patent claims with a rigid frame so as to facilitate manual or automatic handling of the plate device, as is suggested by the prior art of Dannoux et al.

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With respect to claims 10 and 11, while the reference of Dannoux et al. discloses a rigid frame member, the reference is silent as to the material of the frame member and/or thickness of the member. However, based merely on the size of the well plate and/or the desired amount of support, it would have been obvious to one of ordinary skill in the art to determine the optimum material of construction and/or thickness of the frame member while providing the required support for manual and/or automated handling of the well plate.

11. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,556,940 in view of Dannoux et al. (WO 98/19794) taken further in view of Sanadi (US 5,741,463).

The combination of claims 1-21 of U.S. Patent No. '940 and Dannoux et al. has been discussed above.

Claim 12 differs by reciting that the rigid frame is injection molded and includes an array of holes matching the array of wells.

The reference of Sanadi discloses that it is known in the art to provide a tray carrier (16) for supporting a well plate device (3). The tray carrier (16) includes an array of holes (17) matching the array of wells (4) in the well plate device (3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a tray carrier as suggested by the reference of Sanadi with the well plate of the modified claims of the U.S. patent for the known and expected result of providing an alternative means recognized in the art to achieve the same result, supporting a well plate for manual and/or automated handling.

Response to Arguments

12. Applicant's arguments filed 28 Aug. 2003 have been fully considered but they are not persuasive.

Applicants argue that the rejection of the claims over the reference of Tretyakov et al. is improper for the following reasons:

i) The frame disclosed by Tretyakov et al. is only for supporting a gasket and is not for supporting the plastic film outside the heat block.

ii) The plastic film of the reference of Tretyakov et al. has several disadvantages: cannot be removed from the heat block and is not suitable for "rapid PCR".

In response to i) above, while Applicants' characterization of the reference of Tretyakov et al. may be correct, the new claim limitation that the device include a rigid frame for supporting the well plate outside the heat block has been addressed in a new ground of rejection necessitated by amendment to the claim. The new ground of rejection has been made under 35 USC 103 over the reference of Tretyakov et al. in view of Dannoux et al.

In response to ii) above, the combination of the references of Tretyakov et al. and Dannoux et al. address the manual and/or automated handling of the well plate "outside the heat block". Provision of a support member would allow the plate to be handled outside the heat block for automated steps such as sample application and/or analysis of the well contents. With respect to the material not being suitable for "rapid PCR", the sheet material disclosed by the reference of Tretyakov et al. is the same as this instantly claimed, therefore, if the instant material is suitable for "rapid PCR" then the material of the primary reference would also be

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suitable for "rapid PCR". With respect to the use of an apertureless heat block, the prior art rejection of record including the reference of Atwood et al. addresses this newly recited claim limitation.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006 (after 12/16/2003 571-272-1269). The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920 (after 12/16/2003 571-272-1281). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB